8/21/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hans Josef Stauss and Liquan Gao

Serial No.: 09/625,963 Art Unit: 1645

Filed: July 26, 2000 Examiner: DeCloux, A.

For: *IMMUNOTHERAPEUTIC METHODS USING EPITOPES OF WT-1 and GATA-1*

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Responsive to the Office Action mailed May 21, 2001, please consider the following remarks. Submitted with this Response is a Petition for Extension of Time, along with the required fee for a small entity, to extend the period for response for one month, to and including July 23, 2001. The Commissioner is hereby authorized to charge $110.00, the fee for a one month extension of time for a large entity, to Deposit Account No. 50-1868. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge any additional fees to Deposit Account No. 50-1868.

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In the Office Action mailed May 21, 2001, the claims were divided into 30 groups, Group I, claims 1, 4-7, 15 and 19, drawn to the embodiment of a peptide comprising the amino acid sequence of SEQ ID NO:1, or a portion of variant thereof, and pharmaceutical composition thereof, classified in Class 530, subclass 300, and class 514, subclass 15; Group II, claims 1, 4-6, 8, 15 and 19, drawn to the embodiment of a peptide comprising the amino acid sequence of SEQ ID NO:2, or a portion or variant thereof, and pharmaceutical composition thereof, classified in Class 530, subclass 300, and class 514, subclass 15; Group III, claims 1, 4-6, 9, 15 and 19, drawn to the embodiment of a peptide comprising the amino acid sequence of SEQ ID NO:3, or a portion or variant thereof, and pharmaceutical composition thereof, classified in Class 530, subclass 300, and class 514, subclass 15; Group IV, claims 10-14, 16 and 19, drawn to the embodiment of a polynucleotide encoding a peptide comprising the amino acid sequence of SEQ ID NO:1, or a portion or variant thereof, a host cell and an expression vector capable of expressing the peptide, a method of producing the peptide and a pharmaceutical composition comprising the polynucleotide, classified in Class 536, subclass 23.1, Class 435, subclasses 69.1,

252.3, 320.1, and Class 514, subclass 44; Group V, claims 10-14, 16 and 19, drawn to the embodiment of a polynucleotide encoding a peptide comprising the amino acid sequence of SEQ ID NO:2, or a portion or variant thereof a host cell and an expression vector capable of expressing the peptide, a method of producing the peptide and a pharmaceutical composition comprising the polynucleotide, classified in Class 536, subclass 23.1, Class 435, subclasses 69.1, 252.3, 320.1, and Class 514, subclass 44; Group VI, claims 10-14, 16 and 19, drawn to the embodiment of a polynucleotide encoding a peptide comprising the amino acid sequence of SEQ ID NO:1, or a portion or variant thereof a host cell and an expression vector capable of expressing the peptide, a method of producing the peptide and a pharmaceutical composition comprising the polynucleotide, classified in Class 536, subclass 23.1, Class 435, subclasses 69.1, 252.3, 320.1, and Class 514, subclass 44; Group VII, claims 17, 20, and 36-37, drawn to a method of killing target calls in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering a peptide of SEQ ID NO:1, classified in Class 424, subclass 154.1; Group VIII, claims 18, 20 and 36-37, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering a polynucleotide encoding or expressing the peptide of SEQ ID NO:1, classified in Class 514, subclass 44; Group IX, claims 17, 20 and 36-37, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:2 comprising administering a peptide of SEQ ID NO:2, classified in Class 424, subclass 154.1; Group X, claims 18, 20 and 36-37, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising

the amino acid sequence of SEQ ID NO:2 comprising administering a polynucleotide encoding or expressing the peptide of SEQ ID NO:2, classified in Class 514, subclass 44; Group XI, CLASS 17, 20, 36 and 38, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:3 comprising administering a peptide of SEQ ID NO:3, classified in Class 424, subclass 154.1; Group XII, claims 18, 20, 36 and 38, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:3 comprising administering a polynucleotide encoding or expressing the peptide of SEQ ID NO:3, classified in 514, subclass 44; Group XIII, claims 22-27, drawn to a method of producing activated cytotoxic T lymphocytes *in vitro* comprising contacting cells with an antigen of a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in Class 435, subclass 7.2; Group XIV, claims 22-27, drawn to a method of producing activated cytotoxic T lymphocytes *in vitro* comprising contacting cells with an antigen of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in Class 435, subclass 7.2; Group XV, claims 22-27, drawn to a method of producing activated cytotoxic T lymphocytes *in vitro* comprising contacting cells with an antigen of a polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in Class 435, subclass 7.2; Group XVI, claims 28-29, drawn to activated cytotoxic T lymphocytes which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:1, classified in Class 435, subclass 325; Group XVII, claims 28-29, drawn to activated cytotoxic T lymphocytes which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:2, classified in Class 435,

subclass 325; Group XVIII, claims 28-29, drawn to activated cytotoxic T lymphocytes which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:3, classified in Class 435, subclass 325; Group XIX, claim 30, drawn to a T cell receptor which recognizes a cell which aberrantly expresses a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in Class 530, subclass 350; Group XX, claim 30, drawn to a T cell receptor which recognizes a cell which aberrantly expresses a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in Class 530, subclass 350; Group XXI, claim 30, drawn to a T cell receptor which recognizes a cell which aberrantly expresses a polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in Class 530, subclass 350; Group XXII, claims 31-32, drawn to a polynucleotide encoding a T cell receptor which recognizes a cell aberrantly expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in Class 536, subclass 23.5; Group XXIII, claims 31-32, drawn to a polynucleotide encoding a T cell receptor which recognizes a cell aberrantly expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in Class 536, subclass 23.5; Group XXIV, claims 31-32, drawn to a polynucleotide encoding a T cell receptor which recognizes a cell aberrantly expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in Class 536, subclass 23.5; Group XXV, claims 33-34, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering CTL which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:1; Group XXVI, claims 33-34, drawn to a method of killing target cells, that aberrantly express a

polypeptide comprising the amino acid sequence of SEQ ID NO:2 comprising administering CTL which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:2; Group XXVII, claims 33-34, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:3 comprising administering CTL which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:3; XXVIII, claim 35, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering dendritic cells that have been contacted with a peptide comprising the amino acid sequence of SEQ ID NO:1; Group XXIX, claim 25, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:2 comprising administering dendritic cells that have been contacted with a peptide comprising the amino acid sequence of SEQ ID NO:2; and Group XXX, claim 25, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:3 comprising administering comprising dendritic cells that have been contacted with a peptide comprising the amino acid sequence of SEQ ID NO:3.

In response, applicants elect Group I, claims 1, 4-7, 15 and 19 with traverse.

The restriction requirement improperly divides the claims into groups of alleged "inventions" when in fact they should be divided into groups based on subject matter rather than sequence ID, then, at most, applicants are required to elect a single species for initial prosecution. Once the elected species is determined to be patentable, the examiner should then examine the generic claim. Since there are three sequences, each part of a described and claimed

genus, and the claims have been restricted on this basis, a more correct distinction (and indeed, in line with the previous restriction requirements in related cases) would be to divide the claims, at most, into nine groups, as follows:

Group I, claims 1, 4-9, 15 and 19, drawn to a peptide or a portion of variant thereof, and pharmaceutical composition thereof;

Group II, claims 10-14, 16 and 19, drawn to a polynucleotide encoding the peptides of group I, or a portion or variant thereof, a host cell and an expression vector capable of expressing the peptide, a method of producing the peptide and a pharmaceutical composition comprising the polynucleotide;

Group III, claims 17-20, and 36-38, drawn to a method of killing target calls in a patient that aberrantly express a polypeptide as defined by group I;

Group IV, claims 22-27, drawn to a method of producing activated cytotoxic T lymphocytes *in vitro* comprising contacting cells with an antigen of the polypeptides of group I;

Group V, claims 28-29, drawn to activated cytotoxic T lymphocytes which recognizes a cell which aberrantly expresses the polypeptides of group I;

Group VI, claim 30, drawn to a T cell receptor which recognizes a cell which aberrantly expresses a polypeptide of group I;

Group VII, claims 31-32, drawn to a polynucleotide encoding a T cell receptor which recognizes a cell aberrantly expressing a polypeptide of group I;

Group VIII, claims 33-34, drawn to a method of killing target cells, that aberrantly express a polypeptide of group I; and

Group IX, claim 35, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering dendritic cells that have been contacted with a peptide comprising the amino acid sequence of SEQ ID NO:1 (it appears there was an error in this grouping, referring to claims 35 and 25).

Based on this grouping, applicants would then elect the peptide defined by SEQ ID NO:1.

Favorable consideration of claims 1, 4-20 and 22-38 is earnestly solicited.

Respectfully submitted,

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I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Jean Hicks

Date: July 23, 2001

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